

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Veterinary Medicine

Office of New Animal Drug Evaluation

Division of Manufacturing Technologies

Effective Date: December 14, 2018

1. Division of Manufacturing Technologies (DCGCE)

- A. Determines raw material specifications to determine that the ingredients are adequate to insure the identity, strength, quality, and purity of the drug product; reviews the drug product formulation for composition, characteristics, and accuracy.
- B. Evaluates specifications and methods of analysis for the drug product and its components in its dosage forms; recommends product expiration dates from stability data.
- C. Evaluates the total manufacturing and control operations of a drug product as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of a new animal drug application (NADA) and an abbreviated new animal drug application (ANADA).
- D. Coordinates laboratory trials of methods of analysis for drug dosage forms and medicated feed preparations; recommends regulatory methods, and provides technical support when requested by FDA field laboratories.
- E. Participates in the development and implementation of regulations, guidance and policies pertaining to manufacturing issues for drugs and feed additives intended for animal use.
- F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved animal drug products.

G. Evaluates division activities to ensure compliance with the National Environmental Policy Act (NEPA).

2. Authority and Effective Date.

The functional statements for the Division of Manufacturing Technologies were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
Office of New Animal Drug Evaluation
Division of Manufacturing Technologies**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Manufacturing Technologies organization structure depicting all the organizational structures reporting to the Division of Manufacturing Technologies:

Division of Manufacturing Technologies (DCGCE)